200.1138CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Benjamin OSHLACK et al.
Serial No.:	To Be Assigned
Filed:	Herewith
For:	**CONTROLLED RELEASE HYDROCODONE FORMULATIONS**

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Alexandria, VA 22313-1450
Mail Stop: Patent Application

September 11, 2003

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants enclose herewith the Information Disclosure Statement and accompanying Form PTO-1449 (14 sheets) submitted in the parent case; U.S. Application Serial No. 10/016,651, on September 25, 2002. Applicants also enclose herewith the Form PTO-1449 (1 sheet) submitted in the Information Disclosure Statement in U.S. Application Serial No.10/016,651, on March 18, 2003.

Pursuant to 37 CFR 1.98(d), copies of the references of record in the parent application are not enclosed. Copies of the Exhibits to the September 25, 2002 Information Disclosure Statement are also not enclosed as they are of record in the parent application. If it is determined that any of the references or Exhibits are not of record in the parent application, the Examiner is requested to contact the undersigned so that a copy can be forwarded.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered and made of record. It is respectfully submitted that the pending claims are patentable over all of the references made of record at this time.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /HS/

The Examiner's attention is also directed to the following copending patent applications and issued U.S. Patents:

U.S. Patent Application Serial No. 10/392,586, filed March 20, 2003, entitled "Orally Administrable Opioid Formulations Having Extended Duration of Effect," which is a continuation of U.S. Application Serial No. 09/891,882, filed June 26, 2001, entitled "Orally Administrable Opioid Formulations Having Extended Duration of Effect," now Patent No. 6,572,885, issued on June 3, 2003, which is a continuation of Serial No. 09/390,719 filed September 7, 1999, entitled "Orally Administrable Opioid Formulations Having Extended Duration of Effect," now U.S. Patent No. 6,294,195, which is a continuation of U.S. Application Serial No. 08/508,246, filed July 27, 1995, now U.S. Patent No. 5,968,551.

U.S. Patent Application Serial No. 10/162,136 filed June 4, 2002, entitled "Methods of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level", which is a continuation of U.S. Patent Application Serial No. 08/938,898, filed September 26, 1997, entitled "Method of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level," Abandoned, which is a continuation of Serial No. 08/578,668, filed July 22, 1996, now issued U.S. Patent No. 5,672,360, which is a continuation-in-part of Serial No. 08/156,468 filed November 23, 1993, issued as U.S. Patent No 5,478,577.

U.S. Application Serial No. 09/304,694 filed May 4, 1999, entitled "Methods of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level" which is a continuation of Serial No. 08/938,898 filed September 26, 1997, entitled "Method of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level," Abandoned, which is a continuation of Serial No. 08/578,668 filed July 22, 1996, issued as U.S. Patent No. 5,672,360,

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which is a continuation-in-part of Serial No. 08/156,468 filed November 23, 1993, issued as U.S. Patent No 5,478,577.

U.S. Patent Application Serial No. 09/624,530, filed July 24, 2000, entitled "Method of Treating Humans with Opioid Formulations Having Extended Controlled Release," which is a continuation of U.S. Application Serial No. 08/838,368 filed April 8, 1997, now U.S. Patent No. 6,143,322, which is a continuation of U.S. Patent Application Serial No. 08/677,797, filed July 10, 1996, now abandoned, which is a continuation of U.S. Patent Application Serial No. 08/561,829, filed November 27, 1995, now U.S. Patent No. 5,958,459, which is a continuation of U.S. Patent Application Serial No. 08/086,248, filed July 1, 1993, now abandoned.

U.S. Patent Application Serial No. 09/632,718 filed August 4, 2000, entitled "Opioid Formulations Having Extended Controlled Release," which is a continuation of U.S. Application Serial No. 09/225,959, filed January 6, 1999, now U.S. Patent No. 6,103,261, which is a continuation of Serial No. 08/561,829, filed November 27, 1995, now U.S. Patent No. 5,958,459, which is a continuation of U.S. Patent Application Serial No. 08/086,248, filed July 1, 1993, now abandoned.

U.S. Application Serial No. 09/702,283, filed October 30, 2000, entitled "Controlled Release Hydrocodone Formulations", still pending, which claims benefit of U.S. Provisional Patent Application No. 60/162,541, filed October 29, 1999.

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Pursuant to 37 C.F.R. § 1.98 (a)(2)(iii) the Examiner's attention is directed to Exhibit A attached herewith which contains the following:

(i) pending claims of pending application serial no. 10/392,586, which has the same specification as U.S. Patent No. 5,968,551, listed as reference MF on the enclosed Form PTO 1449;

(ii) specifications and claims of pending application serial no and 09/702,283;

(iii) claims of pending application serial nos. 09/304,694 and 10/162,136, which have the same specification as U.S. Patent No. 5,672,360, listed as reference DD on the enclosed Form PTO-1449;

(iv) claims of pending application serial no. 09/624,530, which has the same specification as U.S. Patent No. 5,958,459, listed as reference GC on the enclosed Form PTO 1449;

(v) claims of pending application serial no. 09/632,718, which has the same specification as U.S. Patent No. 6,103,261, listed as reference GD on the enclosed Form PTO 1449.

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200.1138CON

No fee is believed to be due for the submission of this Information Disclosure Statement as it is filed under 37 C.F.R. §1.97(b), before the mailing of a first Office Action on the merits or within three (3) months of the actual filing date. The Commissioner is authorized to charge any additional fee or credit any overpayment to our Deposit Account 50-0552.

Respectfully Submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____

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200.1138US

UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Application of: Benjamin OSHLACK, et al.

Serial No.: 10/016,651

Filed: October 30, 2001

For: **CONTROLLED RELEASE HYDROCODONE FORMULATIONS**

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

September 25, 2002

S i r:

In accordance with the provisions of 37 C.F.R. § 1.97(b), applicants hereby make of record the following: Exhibit A, Form PTO-1449 (14 pages) and the references cited therein.

Attached as Exhibit A is the Court of Appeals for the Federal Circuit Decision and Opinion for the litigation involving the Assignee's U.S. Patent No. 5,672,360 (cited as reference MK in the PTO 1449 Form). It is respectfully requested that this attachment be considered and made of record.

Additionally the Examiner's attention is directed to the following copending patent applications:

Serial No. 09/891,882, filed June 26, 2001, entitled "Orally Administrable Opioid Formulations Having Extended Duration of Effect," which is a continuation of Serial No. 09/390,719 filed September 7, 1999, entitled "Orally Administrable Opioid Formulations Having Extended Duration of Effect," which is a continuation of U.S. Application Serial No. 08/508,246, filed July 27, 1995, now U.S. Patent No. 5,968,551.

Serial No. 09/304,694 filed May 4, 1999, entitled "Methods of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of

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Plasma Drug Level" is a continuation of Serial No. 08/938,898 filed September 26, 1997, entitled "Method of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level," which is a continuation of Serial No. 08/578,668 filed July 22, 1996, issued as the 5,672,360 patent, which is a continuation-in-part of Serial No. 08/156,468 filed November 23, 1993, issued as U.S. Patent No 5,478,577.

Serial No. 09/624,530, filed July 24, 2000, entitled "Method of Treating Humans with Opioid Formulations Having Extended Controlled Release," which is a continuation of U.S. Application Serial No. 08/838,368 filed April 8, 1997, now U.S. Patent No. 6,143,322, which is a continuation of U.S. Patent Application Serial No. 08/677,797, filed July 10, 1996, now abandoned, which is a continuation of U.S. Patent Application Serial No. 08/561,829, filed November 27, 1995, now U.S. Patent No. 5,958,459, which is a continuation of U.S. Patent Application Serial No. 08/086,248, filed July 1, 1993, now abandoned.

Serial No. 09/632,718 filed August 4, 2000, entitled "Opioid Formulations Having Extended Controlled Release," which is a continuation of U.S. Application Serial No. 09/225,959, filed January 6, 1999, now U.S. Patent No. 6,103,261, which is a continuation of Serial No. 08/561,829 described above.

Serial No. 09/702,283, filed on October 30, 2000, entitled "Controlled Release Hydrocodone Formulations," still pending, which claims benefit of U.S. Provisional Patent Application No. 60/162,541, filed on October 29, 1999.

It is respectfully requested that Exhibit A, the PTO 1449 Form (14 pages) and references cited therein be considered and made of record.

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200.1138US

No fee is believed to be due for the submission of this Information Disclosure Statement as it is filed under 37 C.F.R. §1.97(b), before the mailing of a first Office Action on the merits or within three (3) months of the actual filing date. The Commissioner is authorized to charge any additional fee or credit any overpayment to our Deposit Account 50-0552.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By:_____

Robert J. Paradiso
Reg. No. 41,240

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New York, New York 10018
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FORM PTO-1449 (REV. 7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: 200.1138 US	SERIAL NO.: 10/016,651
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT(S): Benjamin OSHLACK, et al.	
		FILING DATE: October 30, 2001	GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	3 6 3 4 5 8 4	01/11/72	Poole	424	21	
	AB	3 8 4 5 7 7 0	11/05/74	Theeuwes, et al.	128	260	
	AC	3 8 7 0 7 9 0	03/11/75	Lowey, et al.	424	19	
	AD	3 9 1 6 8 9 9	11/04/75	Theeuwes, et al	128	260	
	AE	4 3 7 7 5 6 8	03/22/83	Chopra	424	31	
	AF	4 3 8 5 0 7 8	05/24/83	Onda, et al.	427	3	
	AG	4 3 8 9 3 9 3	06/21/83	Schor, et al.	424	19	
	AH	4 4 8 3 8 4 7	11/20/84	Augart	424	22	
	AI	4 5 2 0 1 7 2	05/28/85	Lehmann, et al.	525	369	
	AJ	4 5 4 8 9 9 0	10/22/85	Mueller, et al.	525	123	
	AK	4 5 5 7 9 2 5	12/10/85	Lindahl, et al.	424	19	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AL	0 2 3 5 9 8 6	09/09/87	EPO (A1)	A61K	9/16		
	AM	0 6 6 5 0 1 0	08/02/95	EPO (A1)	A61K	9/26		
	AN	0 2 5 3 1 0 4	01/20/88	EPO (A1)	A61K	9/00		
	AO	0 3 8 8 9 5 4	09/26/90	EPO (A2)	A61K	9/14		
	AP	0 4 1 5 6 9 3	03/06/91	EPO (A1)	A61K	37/02		
	AQ	0 5 3 4 6 2 8	03/31/93	EPO (A1)	A61K	31/485		

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR	Abraham Sunshine et al., "Analgesic Oral Efficacy of Tramadol Hydrochloride in Postoperative Pain," Clin. Pharmacol. Ther., Vol. 51, June 1992, pages 740-746.
	AS	E.Beubler, "Medikamentose Schmerztherapie: Kriterien, Moglichkeiten, Risken," Therapiewoche Osterreich, 7,2 (1992), pages 1-15, English translation.
	AT	Gourlay, et al., "Influence of a High-Fat Meal On The Absorption of Morphine From Oral Solutions," Clin. Pharmacol. Ther., Vol. 46, October 1989, pages 463-468

EXAMINER	/Humera Sheikh/	DATE CONSIDERED	11/10/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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FORM PTO-1449 (REV. 7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: 200.1138US	SERIAL NO.: 10/016,651
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT(S): Benjamin OSHLACK, et al.	
		FILING DATE: October 30, 2001	GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BA	4 7 2 8 5 1 3	03/01/88	Ventouras	424	461	
	BB	4 7 9 7 4 1 0	01/10/89	El-Fakahany	514	356	
	BC	4 8 0 6 3 3 7	02/21/89	Snipes, et al.	71	65	
	BD	4 8 2 8 8 3 6	05/09/89	Elger, et al.	424	419	
	BE	4 8 3 4 9 8 4	05/30/89	Goldie, et al.	424	488	
	BF	5 0 6 8 1 1 0	11/26/91	Fawzi, et al.	424	461	
	BG	4 8 4 4 9 0 7	07/04/89	Elger, et al.	424	465	
	BH	5 0 1 9 3 9 7	05/28/91	Wong, et al.	424	473	
	BI	4 9 8 3 7 3 0	01/08/91	Domeshek, et al.	536	69	
	BJ	5 4 5 6 9 2 3	10/10/95	Nakamichi, et al.	424	489	
	BK	5 4 6 0 8 2 6	10/24/95	Merrill, et al.	424	470	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	BL	0 5 3 5 8 4 1	04/07/93	EPO (A1)	A61K	31/485		
	BM	0 5 4 6 6 7 6	06/16/93	EPO (A1)	A61K	31/60		
	BN	0 5 4 8 4 4 8	06/30/93	EPO (A1)	A61K	9/50		
	BO	0 5 8 0 8 6 0	02/02/94	EPO (A1)	A61K	9/14		
	BP	2 1 7 8 3 1 3	02/11/87	Great Britain (A)	A61K	9/14		

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	BQ	Geoffrey K. Gourlay, et al. "The Reproducibility of Bioavailability of Oral Morphine from Solution Under Fed and Fasted Conditions," Journal of Pain and Symtoms Management,Vol. 6., No. 7, October 1991, Pages 431-436
	BR	Robert F. Kaiko, et al., "Controlled-Release Morphine Bioavailability (MS Contin Tablets) in the Presence and Absence of Food," The Hospice Journal, Vol. 6(4) 1990, pages 17-30.
	BS	Kaiko, et al., "A Single-Dose Study of The Effect of Food Ingestion and Timing of Dose Administration On The Pharmacokinetic Profile of 30-mg Sustained-Release Morphine Sulfate Tablets," Current Terapeutic Research, Vol. 47, No. 5, May 1990, pages 869-878.

EXAMINER	/Humera Sheikh/	DATE CONSIDERED	11/10/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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FORM PTO-1449 (REV. 7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: 200.1138US	SERIAL NO.: 10/016,651
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT(S): Benjamin OSHLACK, et al.	
		FILING DATE: October 30, 2001	GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	CA	5 5 0 8 0 4 2	04/16/96	Oshlack, et al.	424	468	
	CB	5 5 4 9 9 1 2	08/27/96	Oshlack, et al.	424	468	
	CC	5 6 0 1 8 4 2	02/11/97	Barholomaeus	424	464	
	CD	5 5 2 0 9 3 1	05/28/96	Persson, et al.	424	473	
	CE	5 1 2 2 3 8 4	06/16/92	Paradissis, et al.	424	451	
	CF	4 8 6 1 5 9 8	08/29/89	Oshlack	424	468	
	CG	5 4 1 1 7 4 5	05/02/95	Oshlack, et al.	424	456	
	CH	5 5 0 0 2 2 7	03/19/96	Oshlack, et al.	424	476	
	CI	5 5 8 0 5 7 8	12/03/96	Oshlack, et al.	424	468	
	CJ	5 4 7 2 7 1 2	12/05/95	Oshlack, et al.	424	480	
	CK	5 3 7 8 4 7 4	01/03/95	Morella, et al.	424	469	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	CL	WO 92 0 1 4 4 6	02/06/92	PCT (A1)	A61K	9/50		
	CM	WO 92 0 6 6 7 9	04/30/92	PCT (A1)	A61K	9/16		
	CN	WO 93 0 4 6 7 5	03/18/93	PCT (A1)	A61K	31/16		
	CO	WO 93 1 8 7 5 3	09/30/93	PCT (A1)	A61K	9/16		

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	CP	Yokokawa N., et al., "Relationship between plasma concentration of morphine and anlgesic effectiveness," Postgrad Med J, (1991) 67 (Suppl. 2) pages S50-S54.
	CQ	Physicians Desk Reference 1994, 48th Edition, pages 1821-1824.
	CR	D.L. Munday, et al., "Changes in Drug Release Rate 2, Effect of Temperature and Relative Humidity on Polymeric Film Coatings," 5th Cong. Int. Tech. Pharm., 1989, Vol. 2, pp. 55-60.

EXAMINER	/Humera Sheikh/	DATE CONSIDERED	11/10/2008

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LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT(S): Benjamin OSHLACK, et al.	
		FILING DATE: October 30, 2001	GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	DA	4	9	7	0	0	7	5	11/13/90	Oshlack	424	451	
	DB	5	6	5	6	2	9	5	08/12/97	Oshlack, et al.	424	468	
	DC	5	6	7	0	1	7	2	09/23/97	Buxton, et al.	424	495	
	DD	5	6	7	2	3	6	0	09/30/97	Sackler, et al.	424	490	
	DE	5	5	9	3	6	9	5	01/14/97	Merrill, et al.	424	480	
	DF	5	6	6	7	8	0	5	09/16/97	Merrill, et al.	424	473	
	DG	4	9	9	0	3	4	1	02/05/91	Goldie, et al.	424	484	
	DH	5	2	7	3	7	6	0	12/28/93	Oshlack, et al.	424	480	
	DI	4	8	6	1	5	9	8	08/29/89	Oshlack	424	468	
	DJ	4	8	4	4	9	0	9	07/04/89	Goldie	424	480	
	DK	5	2	6	6	3	3	1	11/30/93	Oshlack, et al.	424	468	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	DL	2	1	7	0	1	0	4	07/30/86	United Kingdom (A)	A61K	9/58		
	DM	WO	94	2	2	4	3	1	10/13/94	PCT (A1)	A61K	9/20		
	DN	WO	96	0	0	0	6	6	01/04/96	PCT (A1)	A61K	31/485		
	DO	WO	96	0	1	6	2	9	01/25/96	PCT (A1)	A61K	31/485		
	DP	WO	94	0	5	2	6	2	03/17/94	PCT (A1)	A61K	9/16		

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	DQ	A Protocol for a clinical study entitled "A Randomized, Double-Blind, Parallel-Group Study comparing the Efficacy and Safety of Kapanol® to MS Contin® in the Management of Patients with Moderate to Severe Cancer Pain" ("the Protocol"). The date of the Protocol is indicated as February 10, 1992 and it bears COD No. 14556. The sponsor of the study is indicated to be Faulding Pharmaceuticals, and Australian company.
	DR	Certain Patients Diary Cards, Drug Disposition Records, Case Reports Forms and listing which apparently correlates patient randomization number with the treatment of dosing regimen assigned to each patient. (2003)
	DS	Patient consent forms, apparently for four study participants. (2003)

EXAMINER	/Humera Sheikh/	DATE CONSIDERED	11/10/2008

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FORM PTO-1449 (REV. 7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: 200.1138US	SERIAL NO.: 10/016,651
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT(S): Benjamin OSHLACK, et al.	
		FILING DATE: October 30, 2001	GROUP: 1615

U.S. PATENT DOCUMENTS

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	EA	4	8	3	4	9	8	5	05/30/89	Elger, et al.	424	488	
	EB	5	0	7	1	6	4	6	12/10/91	Malkowska, et al.	424	497	
	EC	5	2	0	2	1	2	8	04/13/93	Morella, et al.	424	469	
	ED	5	1	7	8	8	6	8	01/12/93	Malmqvist, et al.	424	490	
	EE	5	1	3	3	9	7	4	07/28/92	Paradissis, et al.	424	480	
	EF	4	6	0	0	6	4	5	07/15/86	Ghebre-Sellassie, et al.	428	403	
	EG	4	7	0	8	8	7	4	11/24/87	De Haan, et al.	424	470	
	EH	5	0	2	4	8	4	2	06/18/91	Edgren, et al.	424	473	
	EI	5	1	6	9	6	4	5	12/08/92	Shukla, et al.	424	499	
	EJ	5	2	8	3	0	6	5	02/01/94	Doyon, et al.	424	467	
	EK	5	3	2	1	0	1	2	06/14/94	Mayer, et al.	514	25	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	EL	WO	96	1	4	0	5	8	05/17/96	PCT (A1)	A61K	9/14		
	EM	0	5	3	2	3	4	8	03/17/93	EPO (A2)	A61K	31/35		
	EN	0	6	3	6	3	7	0	02/01/95	EP (B1)	A61K	31/485		
	EO	9	0	4	7	7	3	2	07/12/90	Australia				
	EP	9	3	4	1	6	5	4	02/16/95	Australia				

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	EQ	Investigator agreements between the study organizers and certain of the principal investigators.

EXAMINER	/Humera Sheikh/	DATE CONSIDERED	11/10/2008

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FORM PTO-1449 (REV. 7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: 200.1138 US	SERIAL NO.: 10/016,651
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		FILING DATE: October 30, 2001	GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	FA	4	6	0	9	5	4	2	09/02/86	Panoz, et al.	424	19	
	FB	5	2	0	6	0	3	0	04/27/93	Wheatley, et al.	424	490	
	FC	5	2	1	9	5	7	5	06/15/93	Van Bommel, et al.	424	490	
	FD	5	2	4	8	5	1	6	09/28/93	Wheatley, et al.	427	3	
	FE	5	2	5	8	4	3	6	11/20/93	Wheatley, et al.	524	388	
	FF	5	3	8	4	1	3	0	01/24/95	Kamada	424	461	
	FG	5	6	3	7	3	2	0	06/10/97	Bourke, et al.	424	489	
	FH	5	2	8	6	4	9	3	02/15/94	Oshlack, et al.	424	468	
	FI	5	0	0	7	7	9	0	04/16/91	Shell	424	451	
	FJ	5	3	3	0	7	6	6	07/19/94	Morella, et al.	424	490	
	FK	5	6	8	1	5	8	5	10/28/97	Oshlack, et al.	424	494	

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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	FL	0	2	7	1	1	9	3	06/15/88	EPO (B1)	A61K	31/485		
	FM	0	0	9	7	5	2	3	01/04/84	EPO (A2)	A61K	9/26		
	FN	WO	93	1	0	7	6	5	06/10/93	PCT	A61K	9/22		
	FO	0	3	7	7	5	1	8	07/11/90	EPO (A2)	A61K	9/52		
	FP	WO	94	0	3	1	6	1	02/17/94	PCT	A61K	9/52		

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	FQ	Abstracts from the Twelfth Annual Congress of the Oncology Nursing Society, May 1987, In Clinical Nursing Forum Supplement Vol. 14 (2), p112, 1987.
	FR	J. Lapin et al., "Cancer Pain Management with a Controlled Release Oral Morphine Preparation,"Pain and Symptom Manag., Vol. 4 (3), pp.146-151, 1989.
	FS	J. Lapin et al., "Guidelines for Use of Controlled Release Oral Morphine in Cancer Pain Management," Cancer Nursing, Vol. 12 (4), pp. 202-208, (1989).

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LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT(S): Benjamin OSHLACK, et al.	
		FILING DATE: October 30, 2001	GROUP: 1615

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*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	GA	5 4 7 8 5 7 7	12/26/95	Sackler, et al.	424	489	
	GB	6 1 4 3 3 2 2	11/07/00	Sackler, et al.	424	459	
	GC	5 9 5 8 4 5 9	09/28/99	Chasin, et al.	424	490	
	GD	6 1 0 3 2 6 1	08/15/00	Chasin, et al.	424	459	
	GE						
	GF						
	GG						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	GH	0 3 7 7 5 1 8	11/07/90	EPO (A3)	A61K	9/52		
	GI	WO 94 0 3 1 6 0	02/17/94	PCT	A61K	9/32		
	GJ	0 3 7 7 5 1 8	11/07/90	EPO (A2)	A61K	9/52		
	GK	0 3 2 7 2 9 5	08/09/89	EPO (A2)	A61K	9/52		
	GL	0 6 3 6 3 7 0	02/01/95	EPO (A1)	A61K	31/485		
	GM	2 0 8 2 5 7 3	11/10/92	Canada	A61K	047/38		

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	GN	R.K. Kaiko, "The Pre-and Postoperative Use of Controlled-Release Morphine (MS Contin Tablets): A Review of the Published Literature," Medical Department, The Pudue Frederick Company, Royal Society of Medical Services, International Congress, Symposium Services, No. 149, pp. 147-160 (1989).
	GO	H.F. Slowey et al., "Effect of Premedication with Controlled-Release Oral Morphine on Postoperative Pain," Anaesthesia, 1985, Vol. 40, pp. 438-40.
	GP	MS Contin - Frequency of Daily Dosing, January - November 1990
	GQ	
	GR	
	GS	
	GT	

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	HA						
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	HI	2 1 3 1 3 5 0	01/09/94	Canada (A1)	A61K	031/135		
	HJ	0 1 0 8 2 1 8	05/16/84	EPO (A2)	A61K	9/22		
	HK	0 1 4 7 7 8 0	07/10/85	EPO (A2)	A61K	9/32		
	HL							
	HM							

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	HN	R.K. Portenoy, et al., "A Randomized, Double-Blind, Double-Dummy, Crossover Study Comparing the Pharmacolinetics and Pharmacodynamics of Kapanol® Capsules Given Every 24 hours and Every 12 hours with MS Contin® Tablets Given Every 12 Hours in the Management of Patients with Moderate to Severe Chronic Pain" Memorial Hospital IRB Protocol pp. 379-381 (1993)
	HO	7th World Congress on Pain, Abstracts 997-1001, August 26, 1993.
	HP	Advertisement: Roxanol SR., 1988 Roxane Labs, Inc.
	HQ	T. Hunt and R. Kaiko, Comparison of the Pharmacokinetic Profiles of Two Oral Controlled-Release Morphine Formulation in Healthy Young Adults, Clin. Thera., Vol, 13 ,No. 4, pages 482-488, 1991
	HR	S. Bloomfield, et al. Analgesic Efficacy and Potency of Two Oral Controlled-Release Morphine Preparations Clin. Pharmacol. Ther., Vol. 53, No.4, pages 469-478, 1993
	HS	Advertisement: MS Contin 1986, 1987 The Purdue Frederick Company.

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	IA	4	9	3	5	2	4	6	06/19/90	Ahrens	424	490	
	IB	2	7	3	8	3	0	3	03/13/56	Blythe	167	82	
	IC	5	0	7	6	5	6	0	06/25/91	Makino, et al.	424	494	
	ID	5	1	3	2	1	4	2	07/21/92	Jones, et al.	427	196	
	IE	3	9	1	6	8	8	9	11/04/75	Russell	128	145.8	
	IF	4	0	8	8	8	6	4	05/09/78	Theeuwes, et al.	219	121 LM	
	IG	4	0	6	3	0	6	4	12/13/77	Saunders, et al.	219	121 L	
	IH	4	1	3	2	7	5	3	01/02/79	Blichare, et al.	264	25	
	II	4	4	2	1	7	3	6	12/20/83	Walters	424	19	
	IJ	4	8	9	4	2	3	4	01/16/90	Sharma, et al.	424	440	
	IK	5	0	2	3	0	8	9	06/11/91	Sakamoto, et al.	424	502	

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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	IL	WO	93	0	7	8	6	1	04/29/93	PCT (A1)	A61K	9/50		
	IM	WO	92	0	2	2	0	9	02/20/92	PCT (A1)	A61K	9/22	(Abstract)	
	IN	WO	93	0	7	8	5	9	04/29/93	PCT (A1)	A61K	9/16		
	IO	0	2	6	7	7	0	2	05/18/88	EPO (A3)	A61K	9/14		
	IP	0	3	6	1	6	8	0	04/04/90	EPO (B1)	A61K	9/46		

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	IQ	Sustained Release Medications, Noyes Data Corp., pages 3,4,10-15, 96-99, 335-337 (1980).
	IR	Flanders, P., et al. "The Control of Drug Release From Conventional Melt Granulation Matrices," Drug Development and Industrial Pharmacy, Vol. 13, No. 6, pp. 1001-1022 (1987).

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	JA	5 0 3 0 4 0 0	07/09/91	Danielsen, et al.	264	101	
	JB	5 1 2 6 1 4 5	06/30/92	Evenstad, et al.	424	465	
	JC	5 1 9 6 2 0 3	03/23/93	Boehm	424	469	
	JD	5 2 9 2 4 6 1	03/08/94	Juch, et al.	264	37	
	JE	5 1 6 7 9 6 4	12/01/92	Muhammed, et al.	424	482	
	JF	4 4 4 3 4 2 8	04/17/84	Oshlack, et al.	424	22	
	JG	5 6 1 4 2 1 8	03/25/97	Olsson, et al.	424	456	
	JH	5 6 2 9 0 1 1	05/13/97	Illum	424	434	
	JI	4 4 6 4 3 7 8	08/07/84	Hussain	424	260	
	JJ	5 5 0 2 0 5 8	03/26/96	Mayer, et al.	514	289	

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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	JK	0 3 6 1 9 1 0	04/04/90	EPO (A1)	A61K	9/16		
	JL	0 3 7 7 5 1 7	07/11/90	EPO (A2)	A61K	31/52		
	JM	0 4 3 0 2 8 7	06/05/91	EPO (B1)	A61K	9/54		
	JN	0 4 5 2 1 4 5	10/16/91	EPO (A2)	A61K	9/14		
	JO	0 5 5 3 3 9 2	08/04/93	EPO (A1)	A61K	9/50		
	JP	0 5 3 3 2 9 7	03/24/93	EPO (A1)	A61K	9/16		

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	JQ	McTaggart, Celia M., et al., "The evaluation of formulation and processing conditions of a melt granulation process," International Journal of Pharmaceutics, Vol. 19, pp. 139-148 (1984)
	JR	Schaefer, T., et al., "Melt granulation in a laboratory scale high shear mixer," Drug Development and Industrial Pharmacy, Vol. 16, No. 8, pp. 1249-1277 (1990)
	JS	Thomsen, L. Juul, et al., "Prolonged Release Matrix Pellets Prepared by Melt Pelletization I. Process Variables," Drug Development and Industrial Pharmacy, Vol. 19, No. 15, pp. 1867-1887 (1993)
	JT	Thomsen, L. Juul, "Prolonged Release Matrix Pellets prepared by Melt Pelletization II. Hydrophobic Substances as Meltable Binders Vol. 20, No. 77, pp.1179-1197 (1994)

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	KA						
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	KK	0 6 0 9 9 6 1	08/10/94	EPO (A1)	A61K	31/485		
	KL	0 6 3 6 3 7 0	02/01/95	EPO (A1)	A61K	31/485		
	KM	2 0 5 3 6 8 1	02/11/81	Great Britain (B)	A61K	9/22		
	KN	WO 92 0 8 4 5 9	05/29/92	PCT (A1)	A61K	31/485		

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	KO	Thomsen, L. Juul, "Utilizing melt pelletization technique for the preparation of prolonged release products," Pelletization, (material elaborated by assistant prof. Lars Juul Thomsen, Department of Pharmaceutics, Royal Danish School of Pharmacy for the DIE course "Pelletization Technologh," November 1992, 106 pages plus 3 appendices
	KP	Thomsen, L. Juul, "Prolonged Release Matrix Pellets Prepared by Melt Pelletization. Part IV: Drug Particles Size, and Binder Composition," : Pharmaceutical Technology Europa, pp. 19-24 (October 1994)
	KQ	Maccarrone C. et al.; "Single Dose Pharmacokinetics of Kapanol™, a New Oral Sustained-Release Morphine Formulation; Clinical Drug Investigation 1994:7 (5) 262-274
	KR	West R. J., et al., "Single dose pharmacokinetics of a new oral sustained release morphine formulation, Kapanol™ capsules," (Abstract 997) International Association for the Study of Pain, 7th World Congress on Pain. Paris, August 22-27, 1993 (Data on file, Glaxo Australia, F.H. Faulding)

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	LB						
	LC						
	LD						
	LE						
	LF						
	LG						
	LH						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	LI	04 0 8 1 0 8 6	04/02/92	Japan	A61K	9/10	X	
	LJ							
	LK							

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	LL	Gourlay GK, et al., "A comparison of Kapanol™ (A new sustained release morphine formulation), MST Contius® and morphine solution in cancer patients: pharmacokinetics aspects." (Abstract 998) International Association for the Study of Pain, 7th World Congress on Pain Paris, August 22-27, 1993 (Data on file, Glaxo Australia, F.H. Faulding)
	LM	Cherry DA, et al., "A comparison of Kapanol™ (a new sustained release morphine formulation), MST Continus® and morphine solution in cancer patients: Morphine metabolite profiles and renal function." (Abstract 999) International Association for the Study of Pain, 7th World Congress on Pain, Paris August 22-27, 1993 (Data on file, Glaxo Australia, F.H. Faulding)
	LN	Plummer JL, et al., "A comparison of Kapanol™ (a new sustained release morphine formulation) MST Continus® and mophine solution in cancer patients: pharmcodynamic aspects." (Abstract 1000) International Association for the Study of Pain, 7th World Congress on Pain, Paris, August 22-27, 1993 (Data on file, Glaxo Australia, F.H. Faulding)
	LO	Toner G, Cramond T, Bishop, et al., "Randomized double blind, phase III crossover study of a new sustained-release oral mophine fornulation, Kapanol ™ capsules", (Abstract 1001) International Association for the Study on Pain, Paris, August 22-27, 1993 (Data on file, Glaxo Australia, F.H. Faulding)
	LP	Cherry DA, et al., "Once A Day (i.e. 24 Hourly) Kapanol™, A New Sustained Release Morphine Formulation, in the Treatment of Cancer Pain: Morphine Metabolite Profiles"; European Journal of Cancer; Part A General Topics 1995; 31 (S5) Suppl:S184 Abs 884, European Conference on Clinical Oncology and Cancer Nursing, Paris, 29 Oct–2 Nov 1995.

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	MA	5 8 4 3 4 8 0	12/01/98	Miller, et al.	424	484	
	MB	5 8 4 9 2 4 0	12/15/98	Miller, et al.	264	460	
	MC	5 8 7 9 7 0 5	03/09/99	Heafield, et al.	424	464	
	MD	5 8 9 1 4 7 1	04/06/99	Miller, et al.	424	468	
	ME	5 9 6 5 1 6 3	10/12/99	Miller, et al.	424	468	
	MF	5 9 6 8 5 5 1	10/19/99	Oshlack, et al.	424	456	
	MG	5 1 3 3 9 7 4	07/28/92	Paradissis, et al.	424	480	
	MH	5 2 6 6 3 3 1	11/30/93	Oshlack, et al.	424	468	
	MI	5 6 5 6 2 9 5	08/12/97	Oshlack, et al.	424	468	
	MJ	5 6 7 0 1 7 2	09/23/97	Buxton, et al.	424	495	
	MK	5 6 7 2 3 6 0	09/30/97	Sackler, et al.	424	490	
	ML	5 6 8 1 5 8 5	10/28/97	Oshlack, et al.	424	494	
	MM	4 8 4 4 9 0 9	07/04/89	Goldie, et al.	424	480	

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	MN							

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	MO	Gourlay, et al.,; "Once A Day (i.e. 24 Hourly) Kapanol™, A New Sustained Release Morphine Formulation, In The Treatment of Cancer Pain: Pharmacokinetic Aspects", European Journal of Cancer; Part A General Topics 1995:31 (S5) Suppl: S187 Abs 897, European Conference on Clinical Oncology and Cancer Nursing, Paris, 29 Oct-2 Nov 1995
	MP	Broomhead, et al. "Kadian™/Kapanol™-A Once Daily Mophine Formulation" European Journal of Cancer; Part A General Topics 1995:31 (S5) Suppl: S182 Abs 873, European Conference on Clinical Onclology and Cancer Nursing, Paris, 29 Oct-2 Nov 1995
	MQ	Gourlay et al., Proceedings of the 7th World Congress on Pain; A comparison of Kapanol (a New Sustained-Release Morphine Formulation), MST Continus, and Morphine Solution in Cancer Patients: Pharmacolinetic Aspects of Morphine and Morphine Metabolites Progress in Pain Research and Management Volume 2 pp 631-643 (1993)
	MR	Kaiko R.F., "Clinical Protocol and Role of Controlled Release Morphine in the Surgical Patient," Anesthesiology and Pain Management 1991 pp 193-212
	MS	MS Contin - Frequency of Daily Dosing (NDTI) - June, 1991 - May, 1992

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	NC						
	ND						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	NE	0 5 3 2 3 4 8	03/17/93	EP (A3)	C07C	291/04		
	NF	0 5 3 2 3 4 8	03/17/93	EP (B1)	C07C	291/04		
	NG	0 5 3 4 6 2 8	03/31/93	EP (B1)	A61K	31/485		
	NH	0 2 5 3 1 0 4	01/20/88	EPO (B1)	A61K	9/00		
	NI	0 2 3 5 9 8 6	09/09/87	EPO (B1)	A61K	9/16		
	NJ	0 2 3 5 9 8 6	09/09/87	EP (B2)	A61K	9/16		
	NK	0 3 7 7 5 1 8	07/11/90	EPO (A3)	A61K	9/52		
	NL	0 3 8 8 9 5 4	09/26/90	EPO (A3)	A61K	9/14		
	NM	0 3 8 8 9 5 4	09/26/90	EPO (B1)	A61K	9/14		
	NN	0 0 9 7 5 2 3	01/04/84	EPO (B1)	A61K	9/26		

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*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5 8 6 6 1 6 1	02/02/1999	Childers, et al.	424	465	
	AB	6 4 9 1 9 4 5	12/10/2002	Childers, et al.	424	465	
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AL							
	AM							
	AN							
	AO							
	AP							
	AQ							

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR	
	AS	
	AT	

EXAMINER	/Humera Sheikh/	DATE CONSIDERED	11/10/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /HS/